**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| **UNITED STATES OF AMERICA,** | **Criminal No.** 08-CR-10338-WGY |
| **v.** | **Violations:** |
| **DARNELL MARTIN,** | **18 U.S.C. §1001 (false statement) 21 U.S.C. §§331(a), 333(a)(2) and 352 (distribution of a misbranded device)** |
| **Defendant.** | |

## INFORMATION

The United States Attorney charges that:

## GENERAL ALLEGATIONS

At all times material to this Information, unless otherwise alleged:

## BACKGROUND

1. **DARNELL MARTIN** (hereinafter "**MARTIN**"), is an individual currently residing in Illinois. From mid 2004 through approximately November 2007, **MARTIN** was a Territory Manager, and then Regional Manager, of a corporation hereinafter referred to as XYZ Corp ("XYZ"). XYZ was a corporation based in Hopkinton, Massachusetts engaged, *inter alia*, in the manufacture and sale of medical devices for human use, including medical devices for use in healing of fractured or broken bones, including: (a) Device-A, which was an implant to promote growth in certain long bone non-unions; (b) Device-B, which was a putty to promote

bone growth in certain spinal fusions; and (c) Device-C, which was a bone void filler for surgically created osseous defects or osseous defects resulting from traumatic injury.

2. The United States Food & Drug Administration ("FDA") was the agency responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in humans were safe and effective for their intended uses and labeled accurately and in compliance with the law.

3. Device-A, Device-B and Device-C were medical devices within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. §321(h).

4. On October 17, 2001, the FDA, in response to a prior application by XYZ, approved Device-A pursuant to a Humanitarian Device Exemption ("HDE"). The FDA approval was only for "use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed."

5. On April 7, 2004, the FDA, in response to a prior application by XYZ, approved Device-B pursuant to an HDE. The FDA approval was only for "use as an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion."

6. On August 26, 2004, the FDA, in response to a Section 510(k) premarket notification of intent to market a bone void filler product, notified XYZ that it could market the device (Device-C). Device-C was indicated as "a bone void filler for voids or gaps that are not

intrinsic to the stability of the bony structure. It is indicated for surgically created osseous defects or osseous defects resulting from traumatic injury."

7. HDE Exemptions are among the narrowest forms of FDA approvals and impose a number of restrictions on the holder of the HDE. HDEs are for devices designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States. The holder of an HDE is prohibited from selling the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device. Also, under the FDCA, HDEs may only be used in facilities that have established a local institutional review board ("IRB"), which must approve the use of the device before its use.

8. Absent an emergency situation in which an IRB approval could not be obtained in time to prevent serious harm or death to a patient, in order for XYZ to ship Device-A or Device-B to a medical facility, and in turn bill for the devices, XYZ had to have an approval from an IRB approving the labeled use of the device at the relevant medical facility.

9. XYZ gave its sales force the responsibility for obtaining IRB approvals, sometimes motivating them with bonuses for obtaining a certain number of IRB approvals over a particular time period.

10. At relevant times during his employment with XYZ, **MARTIN** was compensated on a percentage commission basis for sales he generated of Device-A, Device-B and Device-C.

11. On or about May 18, 2007, **MARTIN** falsified an IRB approval. This IRB approval purported to be on behalf of an IRB for a medical facility in Wisconsin and purported to

approve the use of Device-A for the period May 16, 2007 through May 16, 2008. This IRB approval purported to be signed by the Chair of the IRB Committee.

12. **MARTIN** prepared this false IRB approval and forged the signature of the IRB Committee Chair, and did so without knowledge or authorization of the IRB Committee or its Chair.

13. **MARTIN** provided this false IRB approval to XYZ in Hopkinton, Massachusetts, and in turn XYZ shipped Device-A and billed for Device-A to the medical facility in Wisconsin.

14. After learning that one of his colleagues had been terminated by XYZ for falsifying IRB approvals in another region of the country, **MARTIN** sent an e-mail to XYZ in Hopkinton, Massachusetts in which he forwarded a purported e-mail from the IRB representative from the medical facility in Wisconsin claiming that the medical facility in Wisconsin had canceled its previous IRB approval for Device-A. The forwarded e-mail was fabricated by **MARTIN** in an effort to avoid detection of his IRB falsification.

15. XYZ has never applied to the FDA for use of Device-A in conjunction with or mixed with Device-C, nor has the FDA ever approved any such use.

16. XYZ has never applied to the FDA for use of Device-B in conjunction with or mixed with Device-C, nor has the FDA ever approved any such use.

17. From approximately April 2006 through at least the March 2007, **MARTIN** and others at XYZ Corp. promoted the sale and use of Device-B to be mixed with and used in conjunction with Device-C. This was an unapproved use.

18. One of the means by which **MARTIN** and others promoted this unapproved use was to prepare and/or distribute to others (including surgeons, surgical staff, XYZ colleagues, or employees of XYZ affiliates) "mixing instructions." There were a variety of mixing instructions used by **MARTIN** and XYZ. One set used by **MARTIN** directed the user to "[e]mpty both of the [Device-B vials] into a specimen container." The mixing instructions then directed the user to "[a]dd 2.5 cc of saline (or the patient's blood) Stir." Then the instructions directed to "[a]dd the contents of [Device-C] into the container." Finally, the instructions said to "[a]dd an additional 3cc of saline (or the patient's blood) to the specimen container. Mix the contents." These documents constituted labeling of the two products, even though neither Device-B nor Device-C was approved by the FDA for combined use.

**Count One:**
**18 U.S.C. §1001 (False Statement)**

19. The allegations contained in paragraphs 1 through 18 are realleged and incorporated herein as if set forth in full.

20. On or about May 18, 2007, in the District of Massachusetts and elsewhere, the defendant,

**DARNELL MARTIN,**

in a matter within the jurisdiction of the executive, legislative and judicial branch of the Government of the United States, knowingly and willfully made a materially false, fictitious and fraudulent statement and representation by stating that an Institutional Review Board for a medical facility in Wisconsin had approved the use of Device-A for the period May 16, 2007 through May 16, 2008.

All in violation of Title 18, United States Code, Section 1001.

**Count Two:**
**21 U.S.C. §§331(a), 333(a)(2) & 352(f)(1) - (Distribution of a Misbranded Device)**

21. The allegations contained in paragraphs 1 through 18 are realleged and incorporated herein as if set forth in full.

22. In or about March 2007, in the District of Massachusetts and elsewhere, the defendant,

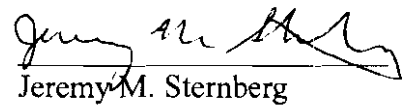
**DARNELL MARTIN,**

with intent to defraud and mislead, did introduce and cause the introduction into interstate commerce, directly and indirectly, quantities of Device-B, a device within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321(h), in combination with Device-C, which was an unapproved use, and therefore misbranded within the meaning of 21 U.S.C.§352(f)(1), in that Device-B's labeling lacked adequate direction for such use.

All in violation of 21 U.S.C. §§331(a), 333(a)(2), and 352(f)(1).

Respectfully submitted,

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

By: 
Jeremy M. Sternberg
Assistant U.S. Attorney